

EXHIBIT D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4 - - -
5
6 IN RE: ETHICON, INC., : MASTER FILE NO.
7 PELVIC REPAIR SYSTEM : 2:12-MD-02327
8 PRODUCTS LIABILITY : MDL 2327
9 LITIGATION :
10 : JOSEPH R. GOODWIN
11 : U.S. DISTRICT JUDGE
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14 March 23, 2016
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16 Oral deposition of KONSTANTIN
17 WALMSLEY, MD taken pursuant to notice, was held at
18 the law offices of Mountainside Hospital, 1 Bay
19 Avenue, Montclair, New Jersey, beginning at 12:23
20 p.m., on the above date, before Ann Marie Mitchell,
21 a Federally Approved Certified Realtime Reporter,
22 Registered Diplomate Reporter and Notary Public.
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24 :
25 :

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1 Q. It goes on to say, mesh-related
2 complications can occur following polypropylene
3 sling replacement, but the rate of complications is
4 acceptably low.

5 Do you agree with that statement?

6 MR. CASPERSON: Objection, form.

7 THE WITNESS: I think from a
8 quantitative statement, that's a true comment.

9 MR. OLIVEIRA: Doctor, if you don't
10 mind, let's take a little break, and we'll move into
11 phase 2.

12 THE WITNESS: Thank you.

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14 (A recess was taken from 1:04 p.m. to
15 1:21 p.m.)

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17 BY MR. OLIVEIRA:

18 Q. If you could I'd ask you to turn to
19 your report, which we have marked as -- I believe as
20 Exhibit 2 in this case.

21 A. Yep.

22 Q. It looks like the first four or five
23 pages of your report are kind of background
24 information and mentions, I guess, the medical
25 records and depositions that you reviewed, along

1 with the medical literature and other documents that
2 you reviewed. Correct?

3 A. Yes.

4 Q. And then you do -- at some point you
5 have a clinical history where you -- it looks like a
6 little chronology where you list a number of
7 different things in her medical history, I guess,
8 that you believe were significant?

9 A. Yes, sir.

10 Q. Then after that, you get into what
11 looks like the couple of general opinions?

12 A. Yes, sir.

13 Q. And then five case-specific opinions
14 or -- yes, it looks like it's five. Is that
15 correct?

16 A. Yes.

17 Q. So let me ask you about your first
18 opinion.

19 Your first general opinion, you state
20 there at the bottom that it's your opinion "the IFU
21 for the TVT in 2002 was not sufficient to enable
22 informed consent from the patient."

23 What do you base that on?

24 A. I base that on my clinical experience
25 with TVT and, for that matter, other polypropylene

1 mesh slings and the IFU that I reviewed that dated
2 back to the time when this sling was implanted.

3 Q. And what do you believe is missing
4 from this IFU that you would put in it?

5 A. Well, there are a lot of potential
6 complications that were not mentioned in the IFU
7 that I've listed in my report.

8 Q. Doctor, would you agree with me that
9 generally, that IFUs typically don't include every
10 potential adverse reaction or complication? Isn't
11 that correct?

12 A. Not necessarily.

13 Q. So you believe that they should have
14 every adverse reaction or every possible reaction to
15 the product?

16 A. I think they should have the majority
17 of them, the ones that are the most likely to occur.

18 For those that are case-report like
19 complications or case-report like findings, I would
20 agree with you, those don't necessarily need to be
21 in the IFU. But certainly the ones that you see
22 with even some regularity or occasional regularity
23 should be mentioned.

24 Q. So tell me, then, which ones do you
25 believe should be in there?

1 A. Well, first, as far as complications
2 to be mentioned, mesh contraction would be one.
3 Dyspareunia. Mesh shrinkage. Scar plate formation.
4 The difficulty in removing mesh.

5 Q. Are those all the ones you feel
6 should be in there?

7 A. That's the majority of them, yes.

8 Q. You would agree with me that a doctor
9 not only has to rely on the IFU for explaining, I
10 guess, the adverse reactions and possible side
11 effects to a plaintiff.

12 Would you agree with that?

13 A. I'm sorry. Could you repeat that
14 question?

15 Q. Well, can doctors also rely, don't
16 they also rely on their experience, their clinical
17 experience in implanting mesh or in this particular
18 case, to rely on -- in providing an informed consent
19 to the plaintiff?

20 A. I think that's a true comment, yes.

21 Q. And do you do that in your practice?

22 A. I do.

23 Q. And do you include things when you go
24 over your informed consent that are not necessarily
25 included in the IFU?

Konstantin Walmsley, M.D.

1

2 CERTIFICATE

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5 I HEREBY CERTIFY that the witness was
6 duly sworn by me and that the deposition is a true
7 record of the testimony given by the witness.

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9 It was requested before completion of
10 the deposition that the witness, KONSTANTIN
11 WALMSLEY, MD, have the opportunity to read and sign
12 the deposition transcript.

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Ann Marie Mitchell

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19 ANN MARIE MITCHELL, a Federally Approved
Certified Realtime Reporter, Registered
Diplomate Reporter and Notary Public

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